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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,133	07/11/2003	Lixiong Li	ARA-US-P1	4427

44702 7590 08/05/2005

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EXAMINER

SAVAGE, MATTHEW O

ART UNIT	PAPER NUMBER
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1724

DATE MAILED: 08/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/618,133

Applicant(s)

LI ET AL.

Examiner

Matthew O. Savage

Art Unit

1724

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-73 is/are pending in the application.
- 4a) Of the above claim(s) 7,8,14,15,20,31,36 and 39-73 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,9-13,16-19,21-30,32-35,37 and 38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 April 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10-14-03</u> | 6) <input type="checkbox"/> Other: _____ |

Applicant's election with traverse of group I, species P1, R1HE1, H3, T1, S2, and C3 in the reply filed on 4-18-05 is acknowledged.

Applicant traversal of the restriction between groups II and I together with IV is not considered persuasive since the apparatuses can be used to carry out another and materially different process as set forth in the restriction requirement. Applicants argument that the method claims (group II) depend from the apparatus claims (group I) is also not persuasive since the apparatus can be used to carry out another and materially different process.

Applicant's traversal between groups III and I together with IV is not considered persuasive since method group III is limited to a process of producing sterile water for injection of which is considered materially different to process of producing drinking water or sterile air. Applicant's argument that separate searches would not be required between groups III, I, and IV is incorrect since examination of group III would require a search in the method subclasses of class 210 whereas examination of groups I or IV would not.

Applicant's traversal between groups I and IV and III and II are not considered persuasive since in each case, the combinations do not require the particulars of the subcombinations, and the subcombinations have separate utility as set forth in the restriction requirement.

Applicant's argument that examination of groups I-IV would not impose an undue burden upon the examiner is not agreed with since each group would require the

searching of different classes and subclasses and because the inventions are independent and distinct from one another as explained the requirement for restriction.

Applicant's comments with respect to the processors (P) and the flow restrictors (R) in the election requirement are noted and agreed with. The argument that claims 37 and 43 do not correspond to species H3 is not agreed with since H3 shown in FIG. 7 shows a reactor 108 that is integral with a unitary homogenizer 116 formed by casting as claimed.

The requirement is still deemed proper and is therefore made FINAL.

References FFF, GGG, HHH, and III on page 3 of the IDS filed on 10-14-03 have not been considered since neither a concise explanation of the relevancy of each reference nor an English translation have been provided.

The drawings are objected to because the reference number "168" should be changed to --184-- in FIGS. 10A and 10B. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several

views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the spring-loaded adjustable pressure relief valve recited in claim 9 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an

application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17 and 18-22, and 24-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 17 and 18, it is unclear as to how a temperature controller can control the temperature of the fluid without the reactor for heating the fluid and the heater for heating the reactor.

With respect to claim 24, it is unclear as to how the process control system is connected to elements of the startup loop assembly.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 10-13, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by GB 2,002,736 to Alhauser.

With respect to claim 1, Alhauser discloses a pump 18 for drawing a fluid from a fluid source 10 through a fluid inlet 44 and pressurizing the fluid; a processor assembly 56 for processing the fluid from the pump; a process control system including a flow splitter 24 disposed between the pump 18 and the processor assembly 56 for diverting a portion of the fluid from the pump, a first flow restrictor 38 for receiving the diverted fluid and directing the diverted fluid to the fluid inlet, a pressure relief valve 36 disposed between the first flow restrictor and the flow splitter, and a second flow restrictor 64 disposed downstream of the processor assembly, the flow splitter, first flow restrictor, second flow restrictor and pressure relief valve being constructed and arranged to coact with each other to be capable of controlling the pressure and flow rate of the fluid in the fluid processor.

Concerning claim 2, Alhauser disclose the process control system as maintaining the pressure of the fluid in the processor assembly at least about the saturation point of the fluid at a predetermined temperature (e.g., assumed to be ambient temperature).

Regarding claim 3, Alhauser disclose the flow splitter 24 is as being a filtration device (e.g., a reverse osmosis filter)

As to claim 4, Alhauser disclose the flow splitter 24 as being a reverse osmosis device.

Regarding claim 10, Alhauser discloses a check valve 16 disposed upstream of the fluid processor 24.

Concerning claim 11, Alhauser discloses a prefilter 14 disposed upstream of the processor assembly 24.

As to claim 12, Alhauser discloses a reverse osmosis device 24 downstream of the prefilter 14.

Regarding claim 13, Alhauser disclose a reverse osmosis device 24 and ion exchange device 48 between the prefilter 14 and processor 56.

Concerning claim 16, Alhauser discloses a processor 56 capable of processing water to produce sterile water for injection (see lines 5-10 of page 1).

Claims 1-4, 10-13, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,072,610 to Gow et al.

With respect to claim 1, Gow et al disclose a pump 20 (see FIG. 1) for drawing a fluid from a fluid source 10 through a fluid inlet and pressurizing the fluid; a processor assembly 50 for processing the fluid from the pump; a process control system including a flow splitter 24 disposed between the pump 20 and the processor assembly 50 for diverting a portion of the fluid from the pump, a first flow restrictor 30 for receiving the diverted fluid and directing the diverted fluid to the fluid inlet, a pressure relief valve 38 disposed between the first flow restrictor and the flow splitter, and a second flow restrictor 60 disposed downstream of the processor assembly, the flow splitter, first flow restrictor, second flow restrictor and pressure relief valve being constructed and arranged to coact with each other to be capable of controlling the pressure and flow rate of the fluid in the fluid processor.

Concerning claim 2, Gow et al disclose the process control system as maintaining the pressure of the fluid in the processor assembly at least about the saturation point of the fluid at a predetermined temperature (e.g., at a temperature of the main sterilizer).

Regarding claim 3, Gow et al disclose the flow splitter 24 is as being a filtration device (e.g., a reverse osmosis filter)

As to claim 4, Gow et al disclose the flow splitter 24 as being a reverse osmosis device.

Concerning claim 11, Gow et al disclose a prefilter 14 disposed upstream of the processor assembly 50.

As to claim 12, Gow et al disclose a reverse osmosis device 24 downstream of the prefilter 14.

Concerning claim 16, Gow et al disclose a processor 50 capable of processing water to produce sterile water for injection.

As to claim 23, Gow et al disclose a heat exchanger 56 for recovering thermal energy, a reactor (e.g., the parallel tube arrangement disposed within the main sterilizer 50), and a heater for heating the reactor (the heating element and bath disposed within the main sterilizer).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alhauser in view of Kasten.

Concerning claim 5, Alhauser fail to specify the flow restrictor 38 as being a fixed setting flow restrictor. Kasten discloses that it is known to control flow in a recycle path of a filtration system with a fixed setting flow restrictor 50. Kasten suggests that such an arrangement is simple and economical to construct. It would have been obvious to have modified the apparatus of Alhauser so as to have included a fixed setting flow restrictor as suggested by Kasten in order to provide a flow restrictor that was simple and economical to construct.

As to claim 6, Kasten discloses a fixed setting flow restrictor in the form of a fixed length capillary tube (see FIG. 1).

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Alhauser in view of Leek, Jr..

With respect to claim 9, Alhauser disclose an adjustable valve 30 but fail to specify the valve as being spring-loaded. Leek, Jr. discloses a spring-loaded valve 61' for a reverse osmosis membrane filter and teaches that such a valve can be used to allow water to escape from the filter housing of an reverse osmosis filter to wash the membrane. It would have been obvious to have modified the valve of Alhauser so as to have included a spring loaded valve as suggested by Leek, Jr. in order to permit water to escape from the housing of the reverse osmosis filter to wash the membrane.

Claims 32-35, 37, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gow et al as applied to claim 23 above, and further in view of Fox.

With respect to claim 32, Gow et al fail to specify a tube-in-tube heat exchanger. Fox discloses a fluid heater including a tube in tube heat exchanger 31, 23 with process fluid (e.g., cooler fluid) flowing through the annular side and the product fluid (e.g., hotter fluid) flowing through the tube side and suggests that such a heater has a high heating efficiency. It would have been obvious to have modified heat exchanger of Gow et al so as to have included the tube-in-tube heat exchanger arrangement as suggested by Fox in order to improve the efficiency of the processor.

Concerning claim 33, Fox discloses a helical tube-in-tube heat exchanger.

As to claim 34, Fox discloses a reactor 16 and heater 17 disposed within the heat exchanger 31, 23.

Regarding claim 35, Fox discloses the reactor 16 and heater 17 as being disposed within a temperature homogenizer 5, 12, 15.

As to claim 37, Fox discloses the temperature homogenizer as including a unitary structure 12 or 15 produced by casting (see lines 65-66 and 76-78 of page 1), the reactor 16 being an integral part of the homogenizer.

Concerning claim 38, Fox discloses the temperature homogenizer as being enclosed by an insulation jacket 20.

Claims 17-19, 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gow et al as applied to claim 23 above, and further in view of Benedict.

Gow et al fail to specify the temperature sensor, temperature controller, touch screen interface, logic controller, pressure transducer, pump controller, endotoxin sensor and signal conditioner, and conductivity cell as recited in claims 17-19, however, Benedict discloses that the use of elements to automatically control and monitor a fluid treatment process is known in the art (see FIG. 1 and paragraphs 23 and 26). It would have been obvious to have modified the apparatus of Gow et al so as to have included the process control elements disclosed by Benedict in order to provide automatic control of the process and to enable monitoring of the process.

Concerning claims 21-22, Gow et al disclose a divert line 70 downstream of the processor 50. Benedict fail to specify placing the flow sensor, conductivity cell, and endotoxin sensor along a divert line, however, such a modification would have been obvious in order to enable monitoring the quality of the finished product in the single pass treatment process of Gow et al.

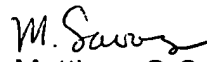
Claims 24-30 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew O. Savage whose telephone number is (571) 272-1146. The examiner can normally be reached on Monday-Friday, 7:00am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Duane Smith can be reached on (571) 272-1166. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Matthew O Savage
Primary Examiner
Art Unit 1724

mos
August 1, 2005



OKay to enter, MS.